IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

BETTY PHELPS and DELBERT PHELPS,

Plaintiffs,

v.

WYETH, INC.; SCHWARZ PHARMA, INC.; PLIVA USA, INC.; NORTHSTAR RX LLC; and ALAVEN PHARMACEUTICAL, LLC,

Defendants.

No. 6:09-cv-6168-TC

OPINION AND ORDER

AIKEN, Chief Judge:

Plaintiffs filed this action on June 12, 2009, for personal injuries allegedly suffered by plaintiff Betty Phelps as a result of being prescribed and ingesting Reglan/metoclopramide for treatment of gastric esophageal reflux disease (GERD). Although plaintiffs alleged several claims, at this stage, the only remaining claim is plaintiffs' assertion that defendant Pliva

failed to update its generic metoclopramide product label in 2003 and 2004 to match the warning on the Reglan brand-name product.

Plaintiff Betty Phelps alleges her doctors prescribed and she ingested metoclopramide tablets from November 2002 to at least August 2009, and that use of the drug caused her to develop the movement disorder tardive dyskinesia. Federal regulations require manufacturers of generic drugs to update their package inserts to match inserts of the name-brand counterpart. Pliva's metoclopramide package insert did not match the Reglan insert after FDA-approved label changes in 2003 and 2004, in that it omitted the warning that **"THERAPY SHOULD NOT EXCEED 12 WEEKS IN DURATION."** Treatment with metoclopramide can cause tardive dyskinesia, a risk that increases with the duration of treatment and the total cumulative dose. Plaintiff's claim has been interpreted as one asserting violation of Oregon's products liability statute. See Or. Rev. Stat. § 30.900.

Although defendants sought summary judgment on multiple occasions previously in this litigation, after finally obtaining plaintiff's medical records, defendant Pliva now asserts that the remaining products liability claim is barred under the applicable statute of limitations. Accordingly, Pliva contends it is entitled to judgment as a matter of law on plaintiff's sole remaining claim.

BACKGROUND

Plaintiff's gastroenterologist, Dr. Craig Chamberlain,

prescribed Reglan (as did her primary care physician) and the prescriptions were allegedly filled with Pliva's generic version in 2002 and from 2004 to 2008.

On March 8, 2007, plaintiff's neurologist, Dr. Andrew Lockfield, noted "definite parkinsonism, which could conceivably just be a Reglan side effect," but he wanted to obtain a brain MRI scan to rule out normal pressure hydrocephalus or other mimics of Parkinson's disease. Clark Decl. Ex. 4 at 4 (doc. 379-4).[1] Plaintiff discussed Parkinson's-like symptoms with Dr. Lockfield and he told her on March 8, 2007, that he thought her use of Reglan was "causing or contributing" to her problems. Betty Phelps Dep. at 18-20 (attached to Clark Decl. (doc. 379-1)). Similar to plaintiff's recollection that Dr. Lockfield discussed problems associated with the use of Reglan, Dr. Lockfield stated that he believed he discussed the Parkinson's-like side effects of the drug. Lockfield Dep. at 30-31 (attached to Clark Decl. (doc. 379-7)). Dr. Lockfield also suggested to plaintiff that she should discuss with her gastroenterologist whether there was an alternative to the Reglan/metoclopramide. Lockfield Dep. at p. 31 (doc. 379-7).

Plaintiff returned to Dr. Lockfield on April 4, 2007. Clark

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[1]Dr. Lockfield also prescribed a trial of Sinemet to support the idea that the Parkinson's-like symptoms were drug-induced and not the result of some other cause. Lockfield Dep. at 35-36 (attached to Clark Decl. (doc. 379-7)).

Decl. Ex. 4 at 6-8. Plaintiff told Dr. Lockfield that the Sinemet improved her symptoms substantially. Id. Ex. 4 at 6. Dr. Lockfield asked plaintiff to discontinue the Reglan and check with Dr. Chamberlain about using a replacement medication for her GERD that would not be expected to cause parkinsonism. Id. Ex. 4 at 7. Plaintiff confirms that Dr. Lockfield told her to stop taking Reglan. Betty Phelps Dep. at 23 (doc. 379-1).

Dr. Chamberlain met with plaintiff on April 16, 2007. Dr. Chamberlain told plaintiff that he was concerned with the use of Reglan "in that it was causing or contributing to ... some of her symptoms." Chamberlain Dep. at 83 (attached to Clark Decl. (doc. 379-5)). Dr. Chamberlain agreed that plaintiff should discontinue Reglan and prescribed a replacement. Id. at 83-84. Dr. Chamberlain believes that both plaintiffs Betty and Delbert Phelps were aware that Reglan was playing a role in her movement disorder. Id. at 84.

On June 14, 2007, Dr. Lockfield noted that after discontinuing metoclopramide, plaintiff developed uncontrollable orofacial movements and he was concerned that this could represent tardive dyskinesia unmasked by stopping Reglan. Clark Decl. Ex. 4 at 9 (doc. 379-4).

On July 19, 2007, Dr. Lockfield noted that the apparent tardive dyskinesia presumably related to the long-term use of Reglan. Id. at 11, 12. Because of the misery plaintiff was suffering, Dr. Lockfield suggested she temporally go back on Reglan

despite the fact that it could worsen tardive dyskinesia in the long-term. Id. at 12. Plaintiff told Dr. Lockfield that she would "rather experience the parkinsonism and accepts the possibility of worsened tardive dyskinesia to get relief of the intolerable symptoms she was experiencing" unresolved by replacement medications. Id.; see also Lockfield Dep. at 74 (doc. 379-7). Plaintiff was aware that the Reglan was thought to be the cause of tardive dyskinesia and that further use might worsen it in the long run, but she was willing to accept that to get short-term relief.

After referral to Dr. Amie Peterson of the Movement Disorder Clinic at Oregon Health and Sciences University on March 24, 2008, plaintiff began tapering off Reglan/metoclopramide and eventually stopped in November of 2009.

DISCUSSION

As noted above, plaintiff's remaining claim is a product liability claim under Or. Rev. Stat. § 30.900. Such an action must be commenced:

> not later than two years after the plaintiff discovers, or reasonably should have discovered, the personal injury or property damage and the causal relationship between the injury or damage and the product, or the causal relationship between the injury or damage and the conduct of the defendant.

O.R.S. § 30.905(1).

This discovery accrual rule means that the time for commencing an action starts running when "(1) the plaintiff knows, or a reasonable person should know, that there is enough chance that the

defendant had a role in causing the plaintiff's injury to require further investigation; and (2) an investigation would have revealed the defendant's role." T.R. v. Boy Scouts of Am., 344 Or. 282, 296, 181 P.3d 758 (2008). As discussed below, the issue is whether plaintiff should have been aware of the causal relationship between the drug and her personal injury prior to June 12, 2007, two years before the commencement of her lawsuit.

Here, plaintiff asserts that she suffered an injury as a result of developing tardive dyskinesia. There may be issues of fact as to when plaintiff learned of this specific diagnosis, raised on June 14, 2007, and its connection to long-term use of metoclopramide. However, there is no issue of fact that plaintiff was or should have been aware of injury suffered as a result of taking the drug, e.g., the parkinsonism, prior to June 12, 2007 and outside of the limitations period.

Plaintiff attempts to dispute that she was told of the connection between this movement disorder and the use of metoclopramide prior to seeing Dr. Peterson. However, no reasonable trier of fact could conclude that she was unaware of the role the drug played in her Parkinson's-like symptoms as early as March 8, 2007, when Dr. Lockfield told her that he thought her use of Reglan was "causing or contributing" to her problems. Further, in April 2007, plaintiff's doctors had informed her to stop taking Reglan/metoclopramide, albeit because of her symptoms of

parkinsonism. Certainly, a reasonable person would know that the product had a role in causing injury and that further investigation was warranted. When plaintiff discontinued the drug on or about April 16, 2007, she developed the orofacial problems associated with tardive dyskinesia within "a very short time ... just a week or two." Betty Phelps Dep. at 25 (doc. 398-2). In addition, the June 14, 2007 chart notes show apparent tardive dyskinesia, and the July 19, 2007 chart notes indicate plaintiff was indeed aware of the risk of tardive dyskinesia associated with the continued use of metoclopramide.

Plaintiff relies on a series of cases involving occupational diseases to assert that the limitations period did not begin to run until plaintiff was aware of a permanent injury, apparently meaning tardive dyskinesia, rather than parkinsonism.[2] See, e.g., Schiele v. Hobart Corp., 284 Or. 483, 490, 587 P.2d 1010 (1978) (the legislature did not intend § 12.110(1) to "be applied in a manner which would require one to file an action for temporary sickness or discomfort or risk the loss of a right of action for permanent injury"). However, even in the area of occupational diseases, the

[2]Plaintiff argues that she was not aware that her symptoms were caused by metoclopramide until Dr. Peterson informed her of such on March 24, 2008. To the extent plaintiff suggests she was not aware of any symptoms associated with the drug until that date, the record does not support such an argument. The medical chart notes and even plaintiff's own deposition testimony show that she knew of the connection between the drug and at least parkinsonism. By at least April 16, 2007, a reasonable person would have known that the drug had a role in causing some injury.

Schiele court rejected the contention that nothing short of a positive diagnosis starts the limitations period. Id. "A plaintiff whose condition has not yet been diagnosed by a physician can have or, in the exercise of reasonable care, could have access to information which requires or would require a reasonable person to conclude she is being seriously or permanently injured." Id. In fact, the Schiele court determined that the limitations period for such injuries begins to run "when a reasonably prudent person associates his symptoms with a *serious* or permanent condition and at the same time perceives the role which the defendant has played in inducing that condition." Id. (emphasis added). As the court further noted:

> Of course, one's condition may deteriorate to the point where a delay in seeking medical attention is no longer reasonable and to further such delay would be to charge the individual with any knowledge which a medical examination would otherwise have disclosed.

Id.

Here, plaintiff's condition deteriorated almost immediately when she discontinued metoclopramide in April 2007, revealing symptoms of tardive dyskinesia. The medical record further reflects that her physicians associated symptoms of tardive dyskinesia with the drug. Clark Decl. Ex. 4 at 9, 11-12 (doc. 379-4).[3] Accordingly,

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[3]Notably, plaintiff chose to continue metroclopramide for 12 months after she learned of its relationship to tardive dyskinesia, even though she asserts that the failure to include this very warning in the drug's label allegedly caused her injury.

to the extent plaintiff delayed seeking medical attention for her orofacial movement disorder when she discontinued metoclopramide in April 2007, no reasonable fact finder could conclude that the apparent delay in discovering the allegedly permanent condition was reasonable.

Regardless, as noted above, plaintiff cannot reasonably claim that the connection of the drug to parkinsonism was not discovered in March or at least April 2007. A disease that causes disturbances in the part of the brain that controls movement - with a characteristic combination of tremor, slowness, rigidity and postural instability - is certainly serious. Moreover, outside the realm of occupational diseases, even if the full extent of injury is not discoverable until after the statute of limitations has run, the limitations period nonetheless begin "to run when a plaintiff knows that he or she has suffered *some* injury because of defendant's acts." Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1156-57 (D. Or. 1989) (analyzing Oregon's discovery accrual rule and Schiele; finding the limitations period began when the plaintiff was informed of temporary injury even though her doctors later discovered it to be permanent) (emphasis in original).

Finally, plaintiff suggests that the limitations period did not begin to run until she discovered that defendant was required to update its label. However, a claim accrues when a plaintiff knows or should know of the potential serious injury and the

defendant who caused such injury. T.R. v. Boy Scouts, 344 Or. at 294-95, 181 P.3d 758 (discussing United States v. Kubrick, 444 U.S. 111 1979)).

Thus, plaintiff in this case discovered an actionable injury outside the limitations period, barring her from bringing the claim after April 16, 2009, if not March 8, 2009. See Raethke v. Oregon Health Sciences Univ., 115 Or. App. 195, 198, 837 P.2d 977 (1992) (A cause of action for personal injury accrues from the date the injury is, or should have been, discovered, not from the time the full extent of damages is ascertained). Plaintiff did not bring this action until June 12, 2009. Accordingly, plaintiffs' action is barred by the statute of limitations.

CONCLUSION

For the reasons stated above, defendant's motion for summary judgment (doc. 377) is granted and judgment shall be entered in favor of defendant PLIVA, Inc. on plaintiff's sole remaining claim.

DATED this 26th day of September, 2014.

Ann Aiken
United States District Judge